

# Effect of clopidogrel and acetylsalicylic acid (ASA) versus clopidogrel or ASA alone on brachial flow mediated vasodilation in patients with coronary artery disease

<b>Submission date</b> 13/12/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2011	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

## Study information

### Scientific Title

Effect of clopidogrel and acetylsalicylic acid (ASA) versus clopidogrel or ASA alone on brachial flow mediated vasodilation in patients with coronary artery disease: a prospective, double-blind, randomised, single-centre trial

**Acronym**

CASSANDRA

**Study objectives**

Treatment with clopidogrel 75 mg per day improves brachial artery flow-mediated dilation of patients with coronary artery disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz) approved on the 20th December 2004

**Study design**

Prospective double-blind randomised single-centre three-armed phase IV clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Stable coronary artery disease

**Interventions**

Clopidogrel 75 mg per day versus clopidogrel 75 mg and acetylsalicylic acid 100 mg per day versus acetylsalicylic acid 100 mg per day for 4 weeks.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Clopidogrel, acetylsalicylic acid (ASA)

**Primary outcome(s)**

Effect of treatment on the absolute change in % flow-mediated dilation (FMD) of the right brachial artery. Evaluated by measurements at the beginning of the trial and at the end of treatment at day 28.

**Key secondary outcome(s)**

Effects of treatment on:

1. Platelet superoxide production
2. Adenosine diphosphate (ADP)-induced platelet aggregation
3. Nitroglycerin-induced brachial artery dilation
4. Inflammatory markers

Evaluated by measurements at the beginning of the trial and at the end of treatment at day 28.

**Completion date**

06/06/2007

**Eligibility****Key inclusion criteria**

1. Men or women, older than 18 years of age
2. Angiographically documented coronary artery disease
3. Absence of angina pectoris within the previous four weeks
4. Written informed consent must be available before enrolment in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Stroke or peripheral arterial revascularisation within the previous 12 weeks
2. Clopidogrel intolerance
3. Planned coronary stent implantation within the next 6 weeks
4. Haemodynamically significant valvular heart disease
5. Known hyper- or hypothyroidism
6. Renal dysfunction (creatinine more than 2.0 mg/dl)
7. Chronic inflammatory intestinal disease or history of malabsorption
8. History of chronic liver disease or pancreatitis
9. Existence of acute gastric ulcers or acute gastrointestinal bleeding
10. Haemoglobin less than 12 g/dl, white blood cells (WBC) less than 4/nl or platelet count less than 100/nl
11. History of organ transplantation
12. Anticipated non-compliance with the protocol
13. Pregnancy
14. Participation in another clinical trial
15. Clinical signs of congestive heart failure or left ventricular ejection fraction less than 40%
16. Uncontrolled hypertension (blood pressure more than 180/105 mmHg)
17. Orthostatic hypotension (supine systolic blood pressure less than 90 mmHg)
18. Treatment with clopidogrel or ticlopidine within the last 28 days prior to study start
19. Initiation of treatment with angiotensin converting enzyme (ACE) inhibitor, statin or calcium channel blocker within previous 2 weeks

**Date of first enrolment**

10/04/2006

**Date of final enrolment**

06/06/2007

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

Department of Medicine II

Mainz

Germany

55131

## Sponsor information

**Organisation**

Johannes Gutenberg-University Mainz (Johannes Gutenberg-Universität Mainz) (Germany)

**ROR**

<https://ror.org/023b0x485>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Bristol-Myers Squibb GmbH & Co. KGaA (Germany)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type

[Results article](#)

Details  
results

Date created

01/01/2011

Date added

Peer reviewed?

Yes

Patient-facing?

No